New study is 'chilling commentary' on future of antibiotics

07/10/2019

The health care market is failing to support new antibiotics used to treat some of the world's most dangerous, drug-resistant "superbugs," according to a new analysis by University of Pittsburgh School of Medicine infectious disease scientists.

In a study published today in *Antimicrobial Agents and Chemotherapy*, a journal of the American Society for Microbiology, investigators used nationwide prescription data to determine that the current annual U.S. sales of new antibiotics to treat carbapenem-resistant Enterobacteriaceae (CRE), one of the world's most insidious drug-resistant bacteria, is about $101 million annually -- significantly short of the $1 billion believed to be necessary to assure the financial viability of a new antibiotic. Even if new anti-CRE agents were used as widely as possible to treat CRE infections, the projected market size is only $289 million.

"New drugs against CRE address a major, previously unmet medical need and are critical to save lives. If the market can't support them, then that is a chilling commentary on the future of antibiotic development," said lead author Cornelius J. Clancy, M.D., associate professor of medicine and director of the mycology program and Extensively Drug Resistant Pathogen Laboratory in Pitt's Division of Infectious Diseases. "Without antibiotics against increasingly resistant bacteria and fungi, much of modern medicine may become infeasible, including cancer chemotherapies, organ transplantation and high-risk abdominal surgeries."

CRE infections are estimated to cause 1.5 to 4.5 million hospitalizations worldwide each year. The Centers for Disease Control and Prevention has classified CRE as urgent threat pathogens

and calls them the "nightmare bacteria." The World Health Organization and Infectious Disease Society of America have designated CRE as highest priority pathogens for development of new antibiotics.

Since 2015, five antibiotics against CRE have gained U.S. Food and Drug Administration (FDA) approval and trials have so far shown three of them to be more effective and less toxic than the previous first-line antibiotics. One of the developers of the new anti-CRE drugs -- the biopharmaceutical company Achaogen -- declared bankruptcy in April because of its steep losses.

After reporting earlier this year that new CRE antibiotics are being prescribed in only about a quarter of infections that warrant them, Clancy and senior author M. Hong Nguyen, M.D., Pitt professor of medicine and director of UPMC's Antimicrobial Management Program, investigated the market needed to make antibiotic development sustainable. They found a shortfall in revenue potential, evidenced by the financial difficulties faced by drug companies that created the new anti-CRE drugs.

"The prudent approach when fighting bacteria is to have multiple treatment options in the pipeline so that when resistance is inevitably developed to the current drug, a new antibiotic is waiting in the wings," said Nguyen. "But we found that market prospects will become even more daunting if more anti-CRE drugs are approved, which is bad news for infectious disease physicians and, more importantly, our patients."

Clancy and Nguyen propose a combination of "push" and "pull" incentives to encourage sustainable antibiotic development, starting with approval of the bilateral DISARM Act, which currently is under consideration in Congress. DISARM would assure full Centers for Medicare and Medicaid Services reimbursement for use of new antibiotics against resistant infections in hospitalized patients, rather than subsuming antibiotic costs into the discounted bundled payment hospitals receive. This would remove the disincentive hospitals face in using more effective but more expensive new agents rather than cheaper, older agents.

There also needs to be a cultural and behavioral change among hospitals and clinicians to encourage faster adoption and appropriate use of new antibiotics, the researchers said. Infectious disease physicians and pharmacists need to take responsibility for educating the wider clinical community about the importance of quickly updating and following guidelines on the best possible antibiotics to be using for their patients.

There was no funding for this study. Clancy and Nguyen report unrelated research funded by various pharmaceutical and medical device companies, detailed in the study manuscript.

Story Source:

Materials provided by **University of Pittsburgh**. *Note: Content may be edited for style and length.*